

(b) *Sponsors.* See 012579 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii), (d)(1)(iii), (d)(2), and (d)(3) of this section. See 021641 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section.

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- (d) * * *
- (1) * * *
- (i) * * *

(B) 120 milligrams trenbolone acetate and 24 milligrams estradiol in 6 pellets with 29 milligrams tylosin tartrate as a local antibacterial in 1 pellet per implant dose.

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Dated: August 24, 1999.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99-22995 Filed 9-2-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Enrofloxacin Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Bayer Corp., Agriculture Division, Animal Health. The supplemental NADA provides for an additional tablet size for enrofloxacin tablets used in dogs and cats for the management of diseases associated with bacteria susceptible to enrofloxacin and for the removal of a tablet size no longer marketed.

EFFECTIVE DATE: September 3, 1999.

FOR FURTHER INFORMATION CONTACT: Dennis M. Bensley, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1705.

SUPPLEMENTARY INFORMATION: Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed supplemental NADA 140-441 Baytril® tablets (enrofloxacin) that provides for 136-milligram (mg) tablet size in addition to 22.7- and 68.0-mg tablets. Furthermore, the sponsor stated that the 5.7-mg tablets are no

longer marketed and has requested the size be deleted. The supplemental NADA is approved as of August 3, 1999, and the regulations are amended in 21 CFR 520.812(a) to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.812 [Amended]

2. Section 520.812 *Enrofloxacin tablets* is amended in paragraph (a) by removing "5.7, 22.7, or 68.0" and adding in its place "22.7, 68.0, or 136.0"

Dated: August 24, 1999.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99-22998 Filed 9-3-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs For Use In Animal Feeds; Semduramicin and Virginiamycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Pfizer, Inc. The NADA provides for using approved single ingredient semduramicin and virginiamycin Type A medicated articles to make combination drug Type C medicated broiler chicken feeds. Approval of the NADA also provides for tolerances for semduramicin residues and an acceptable daily intake (ADI) for semduramicin and for virginiamycin.

EFFECTIVE DATE: September 3, 1999.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141-114 that provides for combining approved Aviax® (22.7 grams per pound (g/lb) semduramicin) and Stafac® (20 or 227 g/lb virginiamycin) Type A medicated articles to make combination drug Type C medicated broiler chicken feeds. The Type C medicated broiler feeds containing 25 parts per million (ppm) (22.7 g/ton (t)) semduramicin and 5 to 15 g/t virginiamycin are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for increased rate of weight gain. The Type C medicated broiler feeds containing 25 ppm semduramicin and 5 g/t virginiamycin are used for the prevention of coccidiosis caused by *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for improved feed efficiency. The Type C medicated broiler feeds containing 25 ppm semduramicin and 20 g/t virginiamycin are used for the prevention of coccidiosis caused by *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for prevention of necrotic enteritis caused by *Clostridium*